I read with interest the draft guidelines on financial relationships. I am quite excited to see this being addressed. I especially like provisions 1.6, 1.7, 2.2, 3.1, 4.2, 4.4, 5.2, and 5.3. I understand you are taking comments until March 2, 2001.

I would like to suggest one addition. Please include some kind of provision that allows each investigator independent access and publishing rights to the entire study data base of any study performed on federal property. This is essential to the integrity of scientific research done in the V.A. system.

Briefly (I don't type that fast), I was a coinvestigator in a multi-site study funded by Marion Merrill Dow on the safety of the nicotine patch in cardiac patients. Our study was essential to the manufacturer's goal of making the patch available over the counter. The scientists insisted on evaluating outcome as well as safety. About 600 patients were randomly assigned to nicotine patch or placebo patch, both with minimal behavioral counseling. Over my protests, someone (the lead investigator or the manufacturer) insisted on separating the study into a safety paper and an efficacy paper. The safety paper, which found no increased risk in the patch group, was published in the NEJM in 1996. The efficacy paper was never published. This is unfortunate because, although we found the patch to be safe in cardiac patients, it was not effective. The patch group had a 10% cigarette abstinence rate at 48 week follow-up while the placebo patch group had a 12% abstinence rate, a nonsignificant difference. Our study confirmed what I had suspected, that the patch alone (i.e., without behavioral skills training) is not more effective than placebo in smoking cessation. I felt our published paper was potentially misleading and implied that the patch alone might be effective by leaving out the long-term follow-up data we had accumulated. I spent the next 3 years trying to get independent access to the data so I could publish the results myself. I was repeatedly denied access. I threatened a FOIA action, made a complaint through our research office, and ultimately wrote a letter to the NEJM detailing what had happened. The editor of the journal sent my letter to the lead investigator and said he would publish it unless we could reach agreement on a joint letter. I was happy to write a joint letter as long as I got access to the data and our data were published. After 3 years of trying, these requests were honored, our joint letter was published in NEJM, and I dropped my complaint.

There are many other examples of industry controlling access and only publishing data that are favorable to their products. This is not science-it is advertising. I am familiar with another multisite patch study conducted by CIBA-GEIGY, in which the data were deemed proprietary and were not released to the investigators because the patch alone had less than a 5% quit rate.

Please save future investigators the anguish and hurdles I encountered. It is not necessary and it does not further our scientific goals. Please include a provision requiring independent access and publishing rights for all investigators who participate in industry funded research. I know this will discourage some industry-government partnerships but the integrity of the scientific product is worth the risk. Even if you have to agree to a 6 month delay for the independent access, it will be better than the current situation.

Sincerely,

David Antonuccio, Ph.D.